K031675

JUN 2 0 2003

Exhibit C

Endoscopy Division

Smith & Nephew, Inc.
150 Minuteman Road, Andover, MA 01810-1031 U.S.A.
Telephone: 978-749-1000
Fax: 978-749-1599

Smith+Nephew

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION as required by the safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew Dyonics® ElectroBlade™ Resector
Date Prepared: May 19,2003

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Karen Provencher
Regulatory Affairs Specialist
978-749-1365 (phone)
978-749-1443 (fax)

C. Device Name

Trade Name:	Smith & Nephew Dyonics® ElectroBlade™ Resector
Common Name:	Arthroscopic Surgery Blade and Electrosurgical Probe
Classification Name:	Electrosurgical cutting and coagulation device

D. Predicate Devices

The Smith & Nephew Dyonics® ElectroBlade™ Resector is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device(s) in commercial distribution:

7205961 4.5mm Full Radius Bipolar ElectroBlade™
7209700 4.5mm Full Radius Elite Bipolar ElectroBlade™

E. Description of Device

The Smith & Nephew Dyonics® ElectroBlade™ Resector combines electrosurgical and shaver technology to provide hemostasis and mechanical cutting in a single instrument.

F. Intended Use

The Smith & Nephew Dyonics® ElectroBlade™ Resector is indicated in arthroscopic surgical procedures of large and small articular cavities for resection and excision of soft and osseous tissues. The Smith & Nephew Dyonics® ElectroBlade™ Resector is effective in tissue resection and hemostasis of bleeding vessels. It is intended for arthroscopic procedures using saline solution, Ringer's lactate or other conductive solutions as an irrigant under direct or video-assisted fiber-optic visualization.

G. Comparison of Technological Characteristics

The Vulcan™ Compatible ElectroBlade™ has the same technological characteristics and intended use as the predicate device, Smith & Nephew Dyonics® ElectroBlade™ Resector.

H. Summary Performance Data

The modified device, performs as well as the unmodified device as demonstrated in the testing performed to the following standards:

- ANSI/AAMI HF18-1993 for Electrosurgical Devices
- IEC 601-1(A1 + A2) Medical Electrical Equipment: Part 1 General Requirements for Safety
- IEC 601-1-2 Medical electrical equipment - Part1: General Requirements for Safety and Part 2: Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC60601-2-2:1998 for Medical Electrical Equipment (Part2-2): Particular Requirements for the Safety of High Frequency Surgical Equipment.

As with the cleared Dyonics® ElectroBlade™ Resectors, these proposed devices have been demonstrated to be in compliance with the following standards:

- ANSI/AAMI ISO 10993-1 for Biological evaluation of medical devices - Part1: Guidance on selection of tests
- ANSI/AAMI ISO 11135 Validation and Routine control of Ethylene Oxide Sterilization

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2003

Ms. Karen Provencher
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K031675
Trade/Device Name: Smith & Nephew Dyonics® ElectroBlade™ Resector
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 29, 2003
Received: May 30, 2003

Dear Ms Provencher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K031675

Device Name: Smith & Nephew Dyonics® ElectroBlade™ Resector

Indications For Use:

The Smith & Nephew Dyonics® ElectroBlade™ Resector is indicated in arthroscopic surgical procedures of large and small articular cavities for resection and excision of soft and osseous tissues. The Smith & Nephew Dyonics® ElectroBlade™ Resector is effective in tissue resection and hemostasis of bleeding vessels. It is intended for arthroscopic procedures using saline solution, Ringer's lactate or other conductive solutions as an irrigant under direct or video-assisted fiber-optic visualization.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031675

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)